DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

April 19, 2001

WARNING LETTER
CHI-28-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Julie Mullen, President/CEO
Accent Health Care
215 W. Washington Street
Hoopeston, IL 60942

Dear Ms. Mullen:

An inspection of your liquid oxygen transfilling facility was conducted on March 28, 2001, by Investigator Susan Yuscius. The inspection documented deviations from the current Good Manufacturing Practice regulations (cGMPs) as outlined in Title 21, Code of Federal Regulations, Parts 210 and 211, in conjunction with your firm's transfilling of Liquid Oxygen, USP. Oxygen is a drug within the meaning of the Federal Food, Drug, and Cosmetic Act (the Act). These deviations cause the drug to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The deviations included:

- Failure to establish written procedures designed to assure that liquid oxygen has the identity and strength it is purported or is represented to possess. All firms are expected to establish and follow detailed written procedures covering all aspects of their operation. These written procedures, including any changes, are to be reviewed, signed and approved by your firm's quality control unit. [21 CFR 211.100(a)]

- Failure to establish adequate batch production and control records for each batch of drug product including documentation that each significant step in the filling operation was performed. The inspection revealed that your firm currently records the information that describes the filling operation on the delivery ticket which includes one check mark that indicates that all of the required information pertaining to the filling operation was "WNL" (within normal limits). It is unacceptable to use a single entry to indicate that all of the required steps in the operation were performed. [21 CFR 211.188]

- Failure to have documentation that demonstrates that the [redacted] employees involved in the transfilling of liquid oxygen have received training for those operations the employees perform. Also, the inspection revealed that there is no documentation that [redacted] of the [redacted] employees responsible for observing the testing of the vehicle mounted vessel after filling by the supplier, received training regarding the analytical method used by your firm's liquid oxygen supplier. [21 CFR 211.25(a)]

- Failure to establish written procedures that discuss a system by which the distribution of each lot of drug product filled by your firm can be readily determined to facilitate its recall if necessary. [21 CFR 211.150(b)]

In addition, these articles of drug are also misbranded under Section 502(o) of the Act in that the drugs are filled in an establishment not duly registered under Section 510 of the Act and the article has not been listed as required by Section 510(j).

This letter and the Form FDA 483, Inspectional Observations, issued to and discussed with you by Investigator Yuscius at the conclusion of the inspection are not intended to be an all-inclusive list of violations found at your firm. It is your responsibility to ensure adherence with all requirements of the Act and that all applicable regulations are being met. Failure to achieve prompt corrections may result in regulatory action without further notice. This may include seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so they may take this information into account when considering the awarding of contracts.

Please notify this office in writing, within 15 working days, of the specific steps you have taken to correct the noted deviations and to prevent the recurrence of similar violations. Also, indicate whether your firm has registered with the FDA as required. Your response should be directed to George F. Bailey, Compliance Officer, at the above address.

Sincerely,

\s\
Raymond V. Mlecko
District Director